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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,651	11/09/2001	Michael Becker	NU-5065 N1	4305

7590

03/09/2004

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EXAMINER

BIANCO, PATRICIA

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 03/09/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/035,651

Applicant(s)

BECKER ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4, 6-8, 12.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION*****Election/Restrictions***

The examiner set forth a restriction requirement that was mailed 11/25/03 (see paper no. 9) requiring election between invention I drawn to claims 1-15, invention II drawn to claims 16-50, and invention III drawn to claims 21-26. Applicant elected with traverse invention I, claims 1-15 (see paper no. 10). However, it has come to the attention of the examiner that a preliminary amendment (see paper no. 1 ½ ) was filed with the application papers, however, the preliminary amendment was not entered before the restriction was mailed. The preliminary amendment cancelled claims 1-26 and added new claims 27-55, for which no restriction is required. Therefore, the restriction requirement has been withdrawn and claims 27-55 have been examined on the merits.

***Information Disclosure Statement***

The information disclosure statement filed 3/18/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The IDS lists "08/033,233" and "09/099,188" under the U.S. Patent Documents section. No copies were in the parent application to review. Upon review of PALM, application 08/033,233 has gone abandoned and therefore has not been considered at this time. Upon review of PALM,

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application 09/099,188 has matured into a patent, US 6,663,743, and has been reviewed and cited by the examiner as a patent (see form PTO-892).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-31 and 35-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Wyslotsky (3,983,994). Wyslotsky discloses a flexible package made of two flexible, plastic sheets sealed about the periphery, forming a first chamber and a second chamber (32/34). The first and second chambers are separated by a peelable seal (30). The two chambers hold two different materials that remain separated until a desired time when the user will mix them by opening the seal. With respect to the claim limitations that the first chamber contains lipids having a specified concentration of a various compound after autoclaving and standing at ambient temperature (see claims 27-30 & 44-55), this limitation is not given any patentable weight since it is the intended use for the container or package. The package of Wyslotsky is inherently capable of holding lipids having various compositions and at various compositions after sterilization and storage. Therefore, the limitations have been met. With respect to claims 36, 37, & 39-42, the limitations of how the peelable seal are formed are considered to be product-by-process and have not been given any patentable weight. "Even though product-by-

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process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Claims 27-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (5,176,634). Smith discloses a multiple compartment container for storage and mixing of different medicaments and diluent. The container is made of flexible, plastic or multi-layer film materials of various composition, which may exclude the use of polyvinyl chloride. The multi-layer film inherently includes up to four layers. The first and second compartments of the container are separated by a peelable seal. With respect to the claim limitations that the first chamber contains lipids having a specified concentration of a various compound after autoclaving and standing at ambient temperature (see claims 27-30 & 44-55), this limitation is not given any patentable weight since it is the intended use for the container or package. The package of Wyslotsky is inherently capable of holding lipids having various compositions and at various compositions after sterilization and storage. Therefore, the limitations have been met. With respect to claims 36, 37, & 39-42, the limitations of how the peelable seal are formed are considered to be product-by-process and have not been given any patentable weight. "Even though product-by-process claims are limited by and defined

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### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Loretti et al. (6,468,259) discloses an analogous multi-compartment, however, its effective filing date is after the effective filing date of the instant application.

Becker et al. (6,663,743) discloses an analogous multi-compartment container having a peelable seal made from a multi-layered film.

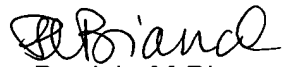
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 6<sup>th</sup>, 2004

  
Patricia M Bianco  
Primary Examiner  
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